



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0001]

Gastrointestinal Drugs Advisory Committee; Cancellation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The meeting of the Gastrointestinal Drugs Advisory Committee scheduled for May 31, 2012, is canceled. This meeting was announced in the Federal Register of March 23, 2012 (77 FR 17078). The meeting is being canceled because the Agency no longer needs to discuss the issues that were originally under consideration in the review of the application. The sponsor of the new drug application (NDA) submitted new information which negated the necessity for the planned meeting. The Agency intends to continue evaluating NDA 200-436 and, as needed, may schedule an Advisory Committee meeting in the future.

FOR FURTHER INFORMATION CONTACT: Minh Doan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: GIDAC@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), to find out further information regarding FDA advisory committee information or visit our Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: May 2, 2012.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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